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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,827	10/01/2001	Shigeki Matsubara		5681

7590 01/07/2005

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/965,827	Applicant(s) MATSUBARA ET AL.	
	Examiner Brian R. Gordon	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 10-25-04.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7-7-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

2. The drawings were received on October 25, 2005. These drawings are acceptable.

Response to Arguments

3. Applicant's arguments filed October 25, 2004 have been fully considered but they are not persuasive. Applicant states the prior art teaches aspiration according to cross-contamination rather than "avoiding levels of carry-over". While applicant is allowed to his own lexicographer the term cross-contamination is understood to be an equivalent to carry-over or narrower in scope.

On page 11 of the remarks, applicant sates the body fluid sample in the **same bottle** in the present invention is analyzed according to avoiding levels of carry-over. The comment is directed to a single sample. Therefore the examiner is unsure what or how the avoiding levels of carry-over are compared. Avoiding levels of what? Different analysis devices, pipettes, or different fluids? It can't be fluids because the fluid is the same fluid from the same bottle resulting in the same level.

Applicant has amended the claims in such a manner that does not remedy the previous clarity problems previously specified. The inclusion of "a plurality of pipettes" has created an additional clarity issue as specified below. As stated below it is unclear what is the relationship of the plurality of pipettes to the analysis items, sample bottle, and the "another sample bottle".

While the clarity issues remains, the examiner has withdrawn the previous art rejections based on applicant's remarks and the examiner's belief/interpretation of what applicant intends to claim as given herein.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are so unclear to the extent where it is difficult to understand the process/method applicant is attempting to claim. There are process limitations missing and not mentioned in the claim which makes it difficult for one to establish what is the relationship of the limitations present within the claims.

The method claim 22 is unclear for the steps are not clear and precise for one to determine how the method is performed. It is not understood if the step of "sampling the body fluid sample contained in a sample bottle using a plurality of pipettes" means **all** of the sample is removed or does sampling mean only a portion of the sample is

removed from the bottle resulting in sample remaining in the bottle. Furthermore is each individual pipette of the plurality of pipettes used to sample a portion of the sample or does that simply mean more than one of the pipettes are employed to sample the body fluid sample? Do the plurality of pipettes remove sample from a single bottle or does each pipette remove sample from a plurality of corresponding bottles? As drafted it appears as if each pipette removes a portion of a sample contained in a single bottle. It is further unclear if the sampled body fluid in the plurality of pipettes is transferred to a second bottle or is the remaining body fluid in the first bottle transferred to a second bottle. While the claim states using a plurality pipettes to sample a body fluid it is not clear what fluid and how the body fluid is transferred to another (second) bottle. The claim recites, "transferring said body fluid sample **in said sample bottle** to another sample bottle". This implies that there is sample fluid remaining in the bottle after the sampling step has been performed by the pipettes and the remaining body fluid in the first bottle is then transferred to another (second) bottle and the sampled body fluid remains in the pipettes. What is "another sample bottle"? Is it a single bottle to which all the fluid is transferred? Or is it applicant's intent to establish that there is a single sample bottle that contains the sample to be transferred and there is a plurality of bottles respectively associated with the plurality pipettes to which sample fluid is transferred thereto from the single sample bottle via respective pipettes? The claim does not specify such, however, the examiner believes applicant intends for the latter to be correct.

Claim 22, line 5, recites, "analyzing said transferred body fluid samples". The preceding text of the claim makes reference to transferring a body fluid sample. As such it is unclear if a single or plurality of samples are transferred. Regardless if applicant intends to transfer the sampled body fluid contained in the plurality of pipettes, the contents of the pipettes are still the single sample that was included in the first bottle. And when transferred to the second bottle from the pipettes the combined portions are still the same original single body fluid sample. The claim should be amended to recite or portray sampling a single first fluid from a bottle by a plurality of pipettes thereby establishing a plurality of samples comprising said first body fluid. If applicant intends for the transferring step to include transferring the established samples from the pipettes, the claim should be amended to clearly recite such.

The first paragraph of claim 22 recites "in a case" as to imply or establish the conditions or a situation in which the analysis is done. If the recited conditions do not occur, then the analysis as claimed is not performed. As such "in a case" when the conditions of that paragraph are not present or do not occur only steps of the first paragraph are valid, required, and performed. To clarify applicant's intent, it is suggest the claim be amend to recite wherein said analysis step comprises analyzing said fluid in said another (or second) bottle using...."

As presently drafted, the claim does not require the analysis as specified in the second paragraph of the claim.

Furthermore, as presently drafted, it is unclear what body fluid sample is analyzed, what body fluid sample is pipetted, what body fluid sample carry-over is

avoided. Is it the body fluid remaining the first bottle, sampled body fluid in the plurality of pipettes, body fluid transferred to the second bottle from the pipettes, body fluid transferred from the first bottle to the second bottle?

If the analysis of one fluid is occurring, then it is unclear how pipetting occurs in relevance to "avoiding levels of carry-over between said body fluid samples" (what body fluid samples?). There is only one body fluid sample present in the second bottle. If there is only one body fluid then there is no need or means for a comparison.

It is unclear why a single body fluid would be aspirated by a plurality of pipettes. The fluid in the first bottle is the same therefore there is no need to compare the avoiding level of portions of the same identical fluid.

Applicant remarks state the invention is directed to using "a pipette" (page 10) last line to sample **different** reagents, samples, DNA, or other liquids in an order determined by the "avoiding level of carry-over" of each liquid. What are analysis items? It is unclear from the claim what the items are related to. Are analysis items considered to be properties of the samples? And if so then the property of the instant claims would be a single item which is the avoiding level of carry-over. If the terms are really synonymous then it is suggested the latter be employed for consistency. Are analysis items different analysis devices? If the analysis items are devices, how are they related to the pipettes and bottles? Is the avoiding level a characteristic of the liquid or the different analysis devices (items)?

It is unclear where/how the basis or level of carryover is established. Is it based on the carryover of different fluids? Is the level of carry over based on different types of pipettes employed for different types of analysis systems/methods?

Claim 23, recites "avoiding levels of carry-over between said samples in advance." There is no antecedent basis in the claim for "said samples".

Claim Interpretations

Based on applicant remarks it appears as if applicant is attempting to claim (in claim 22) a process in which there is a system comprising a plurality/series of analysis devices (analysis items), each analysis device comprising a pipette and a bottle, each of the of pipettes is a sampling element for a respective analysis device, wherein each analysis device performs a different type of analysis process. Each individual pipette is used as a means for sampling a single fluid from a single bottle and transferring the sample into each respective bottle of each analysis device to be analyzed. The order in which each pipette samples fluid from the single bottle is based upon the sensitivity level of each analysis device or the ability to make accurate measurements with the consideration carryover or contamination being present in the sample. As such an analysis device with a high sensitivity samples the fluid first. Therefore the order is established from high sensitivity (most affected by contamination) to lowest.

The confusion appears to arise from applicant's use of the elected terminology "analysis items" and "avoiding levels of contamination". The "analysis items" appear to be individual analysis devices; each having a pipette, (for example device A and device B) and the "avoiding level of contamination" appears to be directed as a characteristic of

the devices ability to make perform accurate analysis of samples when the samples contain contamination (and not the samples themselves). Therefore one may characterize the devices as...device A may be less accurate than device B when using a contaminated sample. As such, it is desirable to allow device B (via it's pipette) to obtain a portion of sample for analysis from a single bottle before allowing device A to sample from the same bottle. The claims do not clearly establish the method or explanation given above.

Allowable Subject Matter

6. Claims 22-26 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. Only if amended/drafted in a form to include the interpretation of the examiner or similar variations thereof.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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